RECORD AND BRIEF

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Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED

AMGEN INC. AND AMGEN MANUFACTURING LIMITED, PETITIONERS,

v.

SANDOZ INC.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONSE AND REPLY BRIEF FOR SANDOZ INC.

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MARCH 31, 2017

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, petitioner/cross-respondent Sandoz Inc. states the following:

Sandoz Inc. is an indirect subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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INTRODUCTION

Sandoz agrees with Amgen that the Biosimilars Act should be applied "as written." Br. 1. But that means applying the statute as written *in its entirety*—not just the parts Amgen rips from context and reads in isolation.

Congress enacted the Biosimilars Act to speed competing biologics to market while preserving incentives for innovation through a 12-year period of exclusivity from biosimilar competition. But to prevent patent litigation from delaying biosimilar cost savings at the end of that exclusivity period, Congress authorized early litigation between applicants and sponsors. In particular, it created new artificial acts of infringement, allowing patent suits potentially years before any actual infringement.

Congress then laid out different routes to pre-approval litigation. The statute outlines procedural steps and specifies litigation-related consequences depending on the parties' actions or inactions. For example, when the statute says that sponsors "shall" bring a patent suit within 30 days (42 U.S.C. § 262(*l*)(6)), it does not mean that a sponsor failing to do so violates the statute and can be compelled to sue. Rather, if a sponsor does not timely sue, its future patent remedies are limited. 35 U.S.C. § 271(e)(6)(A)-(B). In context, each step is not a freestanding command but a mandatory condition precedent to continuing the process.

Amgen addresses only half of this structure. It focuses exclusively on the procedural steps, disregarding the statute's express consequences for not following them. Amgen emphasizes the statute's mandatory language but fails to recognize the contingent nature of its commands: parties *must* take certain steps to start or continue the process, but if they do not, the statute explicitly sets out what happens as a consequence. In place of those consequences, Amgen asks the Court to invent new ones—causes of action for injunctions mandating procedural compliance. The statute "as written" precludes this approach.

The statute as written likewise forecloses Amgen's arguments about the notice of commercial marketing. The provision includes only one timing element—notice "not later than 180 days before" marketing. Yet Amgen seeks to inject a second timing element—no notice until after FDA approval. Had Congress wanted a "before" *and* an "after," it would have said so expressly (as in the very next provision).

Amgen's view is also contrary to the statute's purpose: patent litigation should be early and should not delay biosimilar competition. The notice allows litigation on any unlitigated patents, including newly issued ones. But under Amgen's view, such litigation could never even *begin* until after approval, making resolution impossible before a biosimilar product could be launched. And, perversely, a 180-day stay would apply even when no patents are left to litigate.

Amgen's interpretation extends the 12-year period of exclusivity from biosimilar competition to 12 years and 180 days. Congress focused intensely on the exclusivity period's length. It is inconceivable that Congress extended that period through the word "licensed" in the notice provision, rather than doing so expressly.

Amgen warns that rejecting its interpretations will cause "chaos" and rushed litigation. Amgen claims that an applicant would want to, and could, secretly develop and launch a biosimilar. Given applicants' need for patent certainty before launching products requiring investments of hundreds of millions of dollars and the ample public information about biosimilar development, Amgen's stealth launch scenario is fantasy. It obviously did not worry Congress—as shown by Congress's choice to authorize the sponsor to sue for patent infringement if the applicant does not provide its application or give notice. Congress's choice reflects its (correct) understanding that the sponsor would know when it could sue.

Similarly unpersuasive are Amgen's arguments about two rigid phases of litigation, new patents, and preliminary injunctions. Many of Amgen's hypothetical evils are also possible under its reading. And they ignore litigation realities that formed the backdrop against which Congress legislated. District courts and litigants are fully capable of handling those scenarios through complaint amendments, discovery, and other ordinary litigation tools.

It is Amgen's reading that promotes rushed litigation. Under Sandoz's view, an applicant could withhold its application, triggering immediate litigation on all patents without waiting 250 days to complete the information exchange process. That increases the odds that litigation would finish before FDA approval. And by allowing notice before approval (and, consistent with the statutory text, more than 180 days before marketing), Sandoz's reading would facilitate final judgment on any remaining patents before launch. Amgen's interpretation, by contrast, would squeeze all litigation on any remaining patents into a 180-day period, during which only a preliminary injunction, not a final judgment, could be obtained.

The Federal Circuit's judgment on the notice should be reversed and its judgment on provision of the application should be affirmed.

JURISDICTION

Sandoz incorporates its jurisdictional statement. Br. 1. The dispute remains live. Sandoz Br. 26 n.5; Pet. 36-37; U.S. Cert. Br. 22-24. Sandoz reasonably expects future biosimilars, including with Amgen as sponsor, where: if the subsection (*l*)(8)(A) judgment is reversed, Sandoz will provide pre-licensure notice, and if the subsection (*l*)(2) judgment is affirmed, Sandoz will withhold its application.

STATEMENT

Sandoz relies on its previous Statement (at 7-26).

REPLY IN NO. 15-1039

The Federal Circuit made three independent errors, resulting in 180 days' protection from biosimilar competition beyond the 12 years Congress provided.

I. NOTICE OF COMMERCIAL MARKETING MAY PRECEDE FDA APPROVAL

The text, context, and purpose of the notice of commercial marketing provision all show that notice may be given before FDA approval. Sandoz Br. 30-42; U.S. Br. 27-32.

A. The Text And Context Of Section 262(*l*)(8)(A) Demonstrate That Notice Can Precede FDA Approval

The notice of commercial marketing provision includes only one timing element: notice comes "180 days *before* the date of the first commercial marketing" of the biosimilar. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The provision includes no "after" requirement, *i.e.*, no date after which notice must come.

The very next provision shows how Congress required an action to be both "after" one event and "before" another—*expressly*. Subsection (*l*)(8)(B) states that the sponsor may seek a preliminary injunction on unlitigated patents "[*a*]*fter* receiving the notice [of commercial marketing] under subparagraph (A) and *before* such date of the first commercial marketing." *Id.* § 262(*l*)(8)(B) (emphases added). This before/after structure "shows that Congress knew how to draft the kind of statutory language that [Amgen] seeks to read

into" subsection (*l*)(8)(A), but did not do so. *State Farm Fire & Cas. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 444 (2016). This was the lead textual argument of Sandoz (at 31) and the United States (at 27). Amgen offers no response.

Sandoz explained (at 31-32) that its interpretation is confirmed by the specification that the "subsection (k) *applicant*" gives notice. This shows that the notifying party need only have requested, not received, approval. Amgen responds (at 29) that "[a]n applicant remains the 'person that submits an application under subsection (k)' even after the application is approved." Sandoz agrees. Notice can come before or after approval, and "subsection (k) applicant" describes the notifying entity either way. Under Amgen's view, however, Congress used "subsection (k) applicant" to refer *only* to entities holding granted applications. That would have been a bizarre choice. Adello Biologics Br. 13; *compare* 42 U.S.C. § 262(m)(3) (referring to "the holder of an approved application").

Amgen faults Sandoz for characterizing the provision's purpose as "inform[ing] the sponsor 'that commercial marketing will commence in *at least* 180 days.'" Amgen Br. 35 (quoting Sandoz Br. 39) (emphasis by Amgen). But that purpose is manifest from the text: it contemplates notice "*not later than* 180 days" before marketing. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). Sandoz made this textual point (at 32), yet Amgen offers no response.

Like the Federal Circuit, Amgen's entire textual argument rests on one word in subsection (*l*)(8)(A): "licensed." According to Amgen (at 28), this word refers "to products that have received FDA approval." Sandoz agrees. But showing what "licensed" means does not answer the question here: *when* does the relevant licensing take place? The provision measures its 180-day period backward from the future date of "*the first commercial marketing* of the biological product," at which point it will be "licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). Licensing occurs before the first commercial marketing, not before notice.

This use of "product licensed under" is not "unique." *Contra* Amgen Br. 23. As Sandoz explained (at 34), the Biosimilars Act uses this phrase in the risk-mitigation provision to refer to biosimilars both before and after approval. 42 U.S.C. § 262(k)(5)(C). Amgen does not disagree; instead it contends that this is due to 21 U.S.C. § 355-1(a)(1), which purportedly "extend[s]" risk-mitigation authority to pre-approval products. That is incorrect. Section 355-1(a)(1) did not "extend" anything; it existed *before* the Biosimilars Act. So when Congress used the phrase "products licensed under" in subsection (k)(5)(C), that reflected its background understanding that the phrase imposed no post-approval limitation. So too with subsection (*l*)(8)(A).

Sandoz also showed (at 35) that Section 262 uses "biological product licensed under subsection (a)," "biological product licensed under subsection (k)," and

equivalent phrases to distinguish the two ways biologics are licensed. Subsection (*l*)(8)(A) thus uses "biological product licensed under subsection (k)" to mean the biosimilar, as distinguished from the reference product. Amgen responds (at 29) that because "the provision already refers to '[t]he subsection (k) applicant[,]' * * * [n]o further clarification is necessary." Yet Amgen also argues that subsection (*l*)(8)(A)'s use of "'[t]he subsection (k) applicant' simply distinguishes the party that submitted the application from the reference product sponsor." *Ibid.* The same could just as easily be said of the phrase "biological product licensed under subsection (k)," which mirrors the opening phrase.

Amgen points (at 29) to other provisions "that refer to a product that will be licensed as the 'subject of the application' under subsection (k)." As Sandoz explained (at 36), none of those provisions measures a deadline from a specific future date when the biosimilar will be "licensed." *Accord* U.S. Br. 30. Moreover, using "subject of the application" in subsection (*l*)(8)(A) might have suggested notice could come *only* before approval. Instead, "180-day advance notice can occur either *before* licensing *or* * * * *after* licensing." *Id.* at 29-30.

B. None Of Amgen's Structural Arguments Establishes That Notice Must Await Licensure

Amgen erroneously contends (at 31) that "[t]he structure of §262(*l*) confirms that the marketing notice required by §262(*l*)(8)(A) must be provided after licensure."

Venue. Amgen asserts (at 32) that if an applicant provides its application under subsection (*l*)(2)(A) and simultaneously gives notice of commercial marketing, the applicant could sue immediately in the "venue of its choice." That is incorrect. That hypothetical applicant could not sue because the relevant artificial act of infringement requires a subsection (*l*)(3) list, which would not yet exist. 35 U.S.C. § 271(e)(2)(C)(i). The *sponsor* decides when to provide the subsection (*l*)(3) list and thus ripen the artificial infringement. If the applicant has given notice, the sponsor could simultaneously provide its list and seek a declaratory judgment in a venue of *its* choice. Regardless, that a lawsuit might be filed (by either party) in a proper venue says nothing about the statute's meaning.

Preliminary injunction. Because subsection (*l*)(8)(B) provides that a sponsor may seek a preliminary injunction on any unlitigated patents after receiving notice, Amgen contends the provision "indicates that the notice must come after licensure, when the need for such relief is presented." Br. 32-33. But notice also triggers the right to seek a declaratory judgment, 42 U.S.C. § 262(*l*)(9)(A), and, to the extent a preliminary injunction was also needed, Congress would have understood that its availability would turn on imminence and equitable considerations. *eBay v. MercExchange*, 547 U.S. 388, 392-93 (2006). Indeed, the statute includes no preliminary injunction provision for patents litigated in a subsection (*l*)(6) suit, instead implicitly relying on preexisting authority, *e.g.*, 35 U.S.C. § 283—which would be available only

if imminence and other requirements were satisfied. Similarly, just because subsection (*l*)(8)(B) states a sponsor may *seek* a patent-based preliminary injunction does not mean one will be warranted. And Amgen nowhere explains why such a provision should be read as sub silentio mandating a 180-day injunction without any showing of patent rights. Sandoz Br. 52; *contra* Amgen Br. 51 (speculating Federal Circuit considered equitable factors without mentioning them).

Process patents. Amgen contends that if the government is correct that "'[a]n artificial-infringement claim cannot rest on a manufacturing-process patent alone,'" then notice should await licensure because the sponsor could not assert artificial infringement of a process patent. Amgen Br. 33 (quoting U.S. Br. 25) (alteration by Amgen). But Congress's decision not to make process patents alone sufficient for artificial infringement, 35 U.S.C. § 271(e)(2), shows that Congress did not view them as needing pre-launch adjudication. Unlike a valid product or use patent, which might support an injunction to block launch (and would support an artificial infringement suit), a manufacturing process patent alone is unlikely to block launch because applicants will often be able to show that a different process could be used to make the product. Congress's choice to *deprioritize* litigation on process patents cannot support a reading that delays biosimilar marketing by 180 days to allow litigation on such patents.

New patents. Amgen observes that subsection (*l*)(7) provides for litigation of newly issued or licensed patents after notice. Br. 34. It then worries that

"early" notice could "completely disorder[]" such litigation with a "proliferation of patent suits filed as new patents issue or are licensed by the sponsor." *Ibid.* No textual evidence indicates Congress had any such concern, which ignores litigation basics. Sponsors with pending suits can assert newly acquired patents through amendment. Fed. R. Civ. P. 15. Amgen did just that here. Amgen Br. 57. Or they could file a new suit and consolidate it with the existing one. *Predator Int'l v. Gamo Outdoor USA*, 793 F.3d 1177, 1186-87 (10th Cir. 2015). There is nothing "disordered" about these ordinary litigation practices, which also would be used under Amgen's interpretation whenever new patents issue within 180 days after FDA approval. Moreover, delaying the start of litigation on all such patents until after approval would be contrary to the statute's purpose.

Interchangeability. Amgen points (at 34) to the five potential dates that end the first "interchangeable" biosimilar's exclusivity period. Noting that one date is one year after marketing and another is 18 months after approval, Amgen contends that "Congress expected a gap of roughly 180 days between licensure and marketing." But as Sandoz showed (at 37), Congress would not have chosen two dates that would be (under Amgen's theory) essentially the same, because it is the *earlier* of the five dates that ends the period. Amgen offers no response.

Sandoz also observed (*ibid.*) that six months is longer than 180 days. Had Congress meant to link the notice of commercial marketing and interchangeability

provisions, it would have made the second date "one year plus 180 days" or explicitly referred to the end of the notice period. *Ibid.* Amgen waves this off by positing (at 35) that "Congress gave the applicant a few days' grace period before terminating the incentive for achieving the first interchangeable product." Amgen cites nothing for this "grace period" theory.

Regardless, the interchangeability provisions are immaterial. Amgen asserts (at 35) that because "interchangeable products are a subset of biosimilars," subsection (*l*)(8)(A) should not "appl[y] differently to interchangeable biosimilars than to biosimilars in general." But subsection (*l*)(8)(A) does not apply *at all* to the first marketing of a biosimilar *as an interchangeable*, which typically comes *after* its first marketing as a biosimilar. Sandoz Br. 37-38.

C. Permitting Notice Before FDA Approval Advances Section 262(*l*)(8)(A)'s Purpose

Sandoz explained (at 39-42) that permitting notice before approval advances the statute's purpose of facilitating early resolution of patent disputes. The Federal Circuit's ruling makes the parties wait—potentially for years—before even *starting* litigation on any previously unlitigated patents.

1. Amgen's arguments based on two rigid litigation "phases" are meritless

Amgen agrees that Congress intended early resolution of patent disputes. It contends, however, that this goal was limited to so-called "Phase One" litigation

and that Congress wanted so-called "Phase Two" to happen as late as possible—after the biosimilar's approval. Br. 36-40. Amgen then contends (at 31) that if applicants could provide notice "at any time," then "phase-two litigation" under subsections (*l*)(9)(A) and (*l*)(8)(B) might "subsume" subsection (*l*)(6) "phase-one litigation." Amgen's vision of two rigidly bifurcated "phases" is meritless.

First, overlap between the "phases" would also happen under Amgen's interpretation. Amgen acknowledges (at 38) that "phase-one litigation" may not be concluded by approval. When that happens, even under Amgen's theory, the statute permits applicants to provide notice and trigger "phase two" litigation before "phase one" has ended.

Second, the statute contemplates the possibility of only one "phase" of litigation, where the sponsor does not secure new patents after the information exchange process. It gives the applicant unilateral control over the scope of the subsection (*l*)(6) suit, and the applicant could choose to litigate immediately every patent on the subsection (*l*)(3) lists. Sandoz Br. 42. This demonstrates Congress was not concerned about patent litigation happening too early.

Citing nothing, Amgen suggests (at 15) that subsection (*l*)(5)'s mechanisms for selecting patents to litigate immediately "require the parties to identify patent claims that can meaningfully be adjudicated or otherwise resolved before the FDA determines what, precisely, will be licensed." The statute contains no

such "require[ment]." Rather, it authorizes the applicant to choose the patents for the subsection (*l*)(6) lawsuit. 42 U.S.C. § 262(*l*)(5). Indeed, if the Court considers witness statements from earlier Congresses (the main source of Amgen's "legislative history," *infra* pp. 29-30), one witness explained that the applicant should have this control because it could best determine which patents might block entry and thus require immediate litigation. Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 736 (2010). An applicant that has spent years and hundreds of millions of dollars developing a biosimilar has every incentive to attain patent certainty as early as possible. *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 119 (2007) (statement of Bruce L. Downey, Chairman of the Board, Generic Pharmaceutical Association).

In sum, where the parties engage in the information exchange, the main event is the subsection (*l*)(6) suit, not any mop-up suit that might follow notice.

Third, providing notice merely allows litigation to commence on any not-yet-litigated patents. 42 U.S.C. § 262(*l*)(9)(A). If that occurred during the subsection (*l*)(6) suit's pendency, no "chaos" would ensue. New patents could simply be added to the existing suit (or a new suit coordinated with the existing one). In many cases, there may be *no* such patents.

Apotex Br. 19 (all patents in Apotex-Amgen case were litigated in subsection (*l*)(6) suit).

Finally, contrary to Amgen's hypothesis (at 39), an applicant engaging in the information exchange years before the exclusivity period expires (unlike here) would have no incentive to give notice so early. The information exchange process gives the applicant considerable control, as Amgen's amici acknowledge. Biotechnology Innovation Organization ("BIO") Br. 23. But notice eliminates that control by allowing the sponsor to sue on all patents. A rational applicant would therefore not give notice until nearer approval. Coherus Br. 17-18.

2. *Sandoz's interpretation, not Amgen's, promotes "patent certainty" and minimizes rushed litigation*

Amgen posits (at 47) that subsection (*l*)(9)(A) lifts the bar on declaratory judgment actions on non-litigated patents to "ensure[] that the applicant can obtain patent certainty before launch." But it is Sandoz's reading—not Amgen's—that increases the chance of pre-launch certainty.

Under Sandoz's reading, if exclusivity has not run, notice can be provided early enough to allow for final declaratory judgments on infringement or invalidity on all patents *during the exclusivity period*—thus providing true patent certainty. Under Amgen's interpretation, however, litigation on any patents not adjudicated under subsection (*l*)(6) cannot even *start* until after approval, which is necessarily after exclusivity

expires. Amgen would compress that litigation into 180 days, almost never enough time to secure final judgment in district court, much less to exhaust appeals. Thus, Amgen's interpretation, not Sandoz's, will lead to rushed litigation. *Contra* Amgen Br. 40-41.

This is true despite Amgen's emphasis (at 39) on the immediacy requirement for injunctive relief. Amgen posits that if an applicant gave notice "long before" licensure, the sponsor would not know when harm would be sufficiently immediate for a preliminary injunction. *Ibid.* But in those circumstances, a preliminary remedy would likely be unnecessary because there would be time for final declaratory judgments. If the sponsor prevailed, the applicant would not launch—even absent an injunction—because marketing a product after final declaratory judgment of patent infringement would almost certainly subject the applicant to treble damages, attorneys' fees, and an immediate injunction. 35 U.S.C. § 284; 28 U.S.C. § 2202; *Halo Elecs. v. Pulse Elecs.*, 136 S. Ct. 1923, 1931-33 (2016); *see Samuels v. Mackell*, 401 U.S. 66, 72 (1971) ("[E]ven if the declaratory judgment is not used as a basis for actually issuing an injunction, the declaratory relief alone has virtually the same practical impact as a formal injunction would.").

Moreover, Amgen's concern that a sponsor would have no idea when launch was imminent (and thus when to seek a preliminary injunction) disregards how patent litigation works. Sponsors undoubtedly will propound discovery about the timing of approval and launch. *See* Fed. R. Civ. P. 26, 33. And applicants will

have an ongoing duty to update that information. Fed. R. Civ. P. 26(e)(1). Sponsors would also have access to ample public sources about biosimilars' development. Sandoz Br. 48-51; Biosimilars Council Br. 28-30, 34-35.[1]

Finally, Amgen's discussion (at 36-37) of the possibility of amendments to a biosimilar application provides no support for prohibiting pre-approval notice. Essentially all information submitted while FDA reviews an application is lodged as an "amendment." *See* Center for Biologics Evaluation & Research SOPP 8402, IV.A;[2] SOPP 8001.4, V.L.[3] Indeed, Amgen cites an amendment that merely changed the name of

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[1] Amgen's concern that "[e]ven a speedily issued preliminary injunction or temporary restraining order may not be quick enough to prevent large-scale market incursion by an infringing product" (Br. 41) is misplaced for biosimilars. Unlike small-molecule generics, pharmacies cannot unilaterally switch patients to (non-interchangeable) biosimilars; a prescription for the biosimilar itself is required. FDA, Information for Healthcare Professionals (Biosimilars), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241719.htm (last updated Jan. 12, 2017). Biosimilars thus have much slower market penetration than small-molecule generics. *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 111th Cong. 32, 78-79 (2009) (statement of Federal Trade Commissioner Pamela Jones Harbour and FTC Report on Follow-On Biologic Competition).

[2] https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073461.htm.

[3] https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm063086.htm.

Sandoz's proposed product. Center for Drug Evaluation and Research, Proprietary Name Review(s) (July 23, 2014).[4]

In any event, the sponsor can simply "propound discovery requests under Federal Rules of Civil Procedure 33 and 34 to monitor amendments to the biosimilar application, and, should such an amendment impact the infringement analysis, it can add or remove patents from the case as appropriate." Coherus Br. 16-17. Amgen dismisses this as a "'shoot first, ask questions later' approach" (at 37 n.4), but it is "routinely done in cases involving generic drugs under the Hatch-Waxman Act." Coherus Br. 17. Here, Amgen received all of Sandoz's amendments in discovery yet saw no need to amend its complaint.

II. THE FEDERAL CIRCUIT ERRED BY INVENTING AN EXTRA-STATUTORY RIGHT OF ACTION AND INJUNCTION TO "ENFORCE" THE NOTICE PROVISION

After erroneously concluding that notice must come after FDA approval, the Federal Circuit invented a judge-made cause of action and injunctive remedy to enforce its interpretation. That independent error merits reversal. Sandoz Br. 43-56; U.S. Br. 33-36.

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[4] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000NameR.pdf.

A. That Amgen Originally Sought A State Law Injunction Is Irrelevant

Amgen contends (at 42) that the Court "need not decide whether federal law authorizes an injunction to enforce §262(*l*)(8)(A), because Amgen sought an injunction not under federal law but under California's Unfair Competition Law." Even so, the Federal Circuit *issued* its injunction under federal law, as Amgen suggested it could. Amgen CA Br. 58-59. Indeed, the Federal Circuit's federal injunction rendered "moot" Amgen's "appeal from the dismissal of its unfair competition claim" under state law. Pet. App. 27a-28a. That federal injunction is part of the judgment on review, and provides an independent basis for reversal. Sandoz Cert. Reply 10-12. Indeed, it is the law of the Federal Circuit. *Amgen v. Apotex*, 827 F.3d 1052, 1063-64 (Fed. Cir. 2016). Accordingly, AbbVie's suggestion (at 26) that the Court should remand for the Federal Circuit to consider the remedial consequences of its subsection (*l*)(8)(A) interpretation is meritless. The Federal Circuit has already done so, and that injunction's propriety is one of the questions before the Court. Pet. i-ii.

Amgen's attempted retreat to state law suffers from other defects. First, a California cause of action could not support the judgment, as it would have authorized an injunction only for "conduct occurring within California." *Allergan v. Athena Cosmetics*, 738 F.3d 1350, 1360 (Fed. Cir. 2013). Second, because the scope of a state law judgment would be different and because Amgen's cross-petition did not challenge the

affirmance of dismissal of its state law claims based on the notice provision, this Court could not affirm the injunction on state law grounds. *Nw. Airlines v. County of Kent*, 510 U.S. 355, 364-65 (1994). Third, as Sandoz explained in the Federal Circuit, the comprehensive and intricate federal scheme would preempt any such state law claim. Sandoz CA Br. 59; *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 350 (2001); Pet. App. 67a n.4.

B. Amgen Has No Right To A Federal Injunction

Amgen abandons its argument that the injunction here was an injunction pending appeal. Amgen Cert. Opp. 29-30. Instead, Amgen points to the Biosimilars Act's litigation-triggering provisions, contending they authorize an injunction ordering compliance with subsection (*l*)(8)(A). Amgen Br. 45; *see* Genentech Br. 5. But those provisions allow litigation to seek remedies for substantive violations of valid patent rights, not Biosimilars Act procedural violations.

1. A cause of action for patent infringement cannot support an injunction to "enforce" the notice provision

Although Amgen does not cite it, there is a single cause of action under which Biosimilars Act-related litigation may be maintained: 35 U.S.C. § 281. *See* U.S. Br. 4, 6, 16, 18, 22-23. It provides that "[a] patentee shall have remedy by civil action *for infringement* of his patent." 35 U.S.C. § 281 (emphasis added). This cause of action "specifies the conduct for which

defendants may be held liable." *Cent. Bank of Denver v. First Interstate Bank*, 511 U.S. 164, 179 (1994). And the liability-triggering conduct for Section 281 is violation of substantive patent rights—not failure to follow the Biosimilars Act's procedural steps.

Each of the Act's litigation-related provisions controls access to the Section 281 cause of action and shapes the scope of that litigation. Under certain circumstances, for example, the statute makes "submi[ssion]" of a biosimilar application an artificial "act of infringement," actionable under Section 281 where the application's "purpose" is "to obtain approval" of a biologic "*claimed in a patent.*" 35 U.S.C. § 271(e)(2)(C) (emphasis added); *see* U.S. Br. 21-22. Other provisions control the suit's timing, scope, and remedies. 42 U.S.C. § 262(*l*)(2)-(9); 35 U.S.C. § 271(e)(4), (6). But all such litigation necessarily involves a "civil action *for infringement*" of a patent, 35 U.S.C. § 281 (emphasis added), or anticipatory defense to such an action. *Id.* § 271(e)(2); 42 U.S.C. § 262(*l*)(6), (8)(B), (*l*)(9) (all referring to patent infringement actions).

In a properly filed action *for patent infringement* under these provisions, a court would have equitable power to remedy that substantive wrong, *e.g.*, to grant "injunctive relief" against an "infringer" to prevent infringement. 35 U.S.C. § 271(e)(4)(B). But Amgen cites no authority for the proposition that an express cause of action to enforce one requirement (here, prohibition

of patent infringement) authorizes an injunction involving an entirely different one (here, provision of notice).[5]

Indeed, Amgen's cited authority says just the opposite. Amgen Br. 44 (citing *Alexander v. Sandoval*, 532 U.S. 275 (2001)). In *Sandoval* a private cause of action allowed individuals to sue for intentional discrimination. 532 U.S. at 279-80. The Court held, however, that this cause of action did not authorize suit for a *different* violation—disparate impact discrimination. *Id.* at 285-86. The same analysis applies here.

Sandoz explained (at 54-55) that the authority cited in *Apotex* likewise does not support Amgen's mix-and-match approach. Amgen makes no attempt to rehabilitate that precedent, instead citing (at 46) two other decisions (from a purported "legion") supposedly establishing that "courts generally possess power to enjoin violations of the law." But neither decision stands for that breathtakingly broad principle.

In *Califano v. Yamasaki*, it was uncontested that the court had express statutory jurisdiction to review the adequacy of the procedures used to make an administrative determination. 442 U.S. 682, 705 (1979).

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[5] Genentech's reliance (at 26-27) on 35 U.S.C. § 283 is likewise inapposite. That provision authorizes "injunctions in accordance with the principles of equity to prevent the violation of *any right secured by patent*." 35 U.S.C. § 283 (emphasis added); *see Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 674 (Fed. Cir. 1990) (violation of patent right is "necessary predicate" to Section 283 injunction). Subsection (*l*)(8)(A) creates *no* right (Sandoz Br. 44), much less one "secured by patent," 35 U.S.C. § 283.

The Court held that the jurisdictional provision also conferred the power to issue an injunction requiring proper procedures. *Ibid.* In *United States v. Paradise*, 480 U.S. 149 (1987) (plurality), Section 1983 provided an express cause of action for a "suit in equity" for "redress" of constitutional violations. 42 U.S.C. § 1983; *see Paradise v. Prescott*, 767 F.2d 1514, 1516-17 (11th Cir. 1985), *aff'd sub nom. Paradise*, 480 U.S. 149. In both cases (as in those cited in *Apotex*), an express cause of action provided authority to redress *the relevant substantive violation*. Here, there is none.[6]

2. *There is no implied right of action to enforce the notice provision*

Amgen contends (at 50) that even if no express cause of action supports an injunction to enforce the notice provision, the Court should fashion one. Yet Amgen does not come close to justifying creation of a cause of action and injunctive remedy that Congress omitted.

First, as Sandoz showed (at 44), the notice provision creates no private right—it is purely procedural, and the only substantive rights at issue are patent rights. Amgen offers no response. Second, Amgen fails to show congressional intent to create an injunctive

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[6] Nor does the All Writs Act provide such authority. *Contra* Janssen Br. 25; BIO Br. 28. Where, as here (*see* 42 U.S.C. § 262(*l*)(9)(B)), "a statute specifically addresses the particular issue at hand, it is that authority, and not the All Writs Act, that is controlling," even if "compliance with [those] statutory procedures appears inconvenient or less appropriate." *Pa. Bureau of Corr. v. U.S. Marshals Serv.*, 474 U.S. 34, 43 (1985).

remedy. Amgen contends (at 50) that divining such intent "should be straightforward" because the "provision plays an essential role in the procedural framework Congress enacted, and the government does not enforce it." Amgen cites no authority for its "essential role" test, nor does it explain how that standard would be judicially administrable.

Amgen suggests that when Congress regulates conduct between private parties, courts can invent causes of action and remedies—so long as the government plays no enforcement role. Br. 43-44; *see* Genentech Br. 11-15. Amgen cites no authority for such judicial license. It is now recognized as a separation of powers principle that *only* Congress may provide statutory rights and remedies. Congress's decision not to make the Biosimilars Act's procedural steps enforceable by the government (and instead to provide only patent litigation-channeling consequences) does not permit courts to invent their own causes of action and extra-statutory remedies.

a. The statute's express consequences foreclose adding others

The absence of any implied cause of action is confirmed by the Act's express consequences when an applicant does not give notice—a declaratory judgment action by the sponsor, but not the applicant. 42 U.S.C. § 262(*l*)(9)(B); *see* Sandoz Br. 46-47. Amgen's amicus BIO acknowledges (at 26) that Congress intended the declaratory judgment provisions in subsection (*l*)(9) "to penalize and discourage non-compliance by either

party." Congress therefore calibrated the incentives; courts should not invent their own remedies to restrike that balance.

Amgen contends (at 47) that subsection (*l*)(9)(B) "does not purport to *remedy* a marketing-notice violation" but merely "preserv[es] the sponsor's background right to file a declaratory-judgment action." There is no such "background right." It is the Biosimilars Act's artificial infringement provisions that permit pre-approval suits, and subsection (*l*)(9) controls access to them. Sandoz Br. 11. And whether subsection (*l*)(9)(B) is "remedial" is immaterial: Congress anticipated non-provision of notice and expressly provided the consequence. That consequence is not an injunction enforcing notice.

In any event, Amgen misapprehends the statute in asserting that subsection (*l*)(9)(B) is not a "remedy." As Amgen itself recognizes (at 36), notice merely triggers the ability to institute patent litigation: a declaratory judgment (for either applicant or sponsor) or preliminary injunction (for the sponsor). The statute also triggers the ability to pursue certain patent remedies if the applicant does *not* give notice: the sponsor, but not the applicant, may seek a declaratory judgment and injunctive relief on certain patents. 42 U.S.C. § 262(*l*)(9)(B); *see* 28 U.S.C. § 2202. Thus, the statutory consequence for not satisfying one provision that would have triggered patent litigation (subsection (*l*)(8)(A)) is to trigger patent litigation a different way (subsection (*l*)(9)(B)). Congress's specification of that alternative pathway to patent remedies forecloses

Amgen's judge-made, non-patent-based injunction. *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989).

Contrary to Amgen's contention (at 50), adhering to the statute's specified consequences does not render the notice provision a "nullity." If the applicant does not provide notice, it cannot obtain patent certainty by seeking a declaratory judgment on any unlitigated patents. *Compare* 42 U.S.C. § 262(*l*)(9)(A) (notice lifts bar on actions by sponsor *and* applicant), *with id.* § 262(*l*)(9)(B) (failure to give notice lifts bar only for sponsor). If the sponsor does not seek a declaratory judgment, the applicant may be forced to launch at risk, without knowing whether it faces damages. If any significant patents remain, an applicant would have powerful incentives to provide notice.

Amgen also contends (at 47) that subsection (*l*)(9)(B) "would be a wholly ineffective remedy for a marketing-notice violation." This policy-based objection is misplaced. *Sandoval*, 532 U.S. at 286-87 ("courts may not create" a cause of action, "no matter how desirable that might be as a policy matter, or how compatible with the statute"). In any event, there are myriad real-world ways that a sponsor will learn of pending biosimilar applications before FDA approval. Sandoz Br. 48-51; Biosimilars Council Br. 28-30, 34-35. Armed with such knowledge, sponsors could simply ask applicants if they intend to provide notice. If an applicant's answer were unsatisfactory, a sponsor would have a good-faith basis for asserting the applicant was going to "fail[] to complete an action"

required by subsection (*l*)(8)(A) and could bring a pre-launch infringement action for declaratory judgment (and, if necessary, a patent-based preliminary injunction). 42 U.S.C. § 262(*l*)(9)(B); 28 U.S.C. § 2202; 35 U.S.C. § 283; *infra* pp. 40-41.

Finally, Amgen observes (at 48-49) that the subsection (*l*)(9)(B) consequence for not providing notice is inapplicable where the applicant withholds its application. But under those circumstances, subsection (*l*)(9)(C) has *already* authorized sponsors to seek a declaratory judgment on all patents. Amgen contends (at 49) that the lack of an *additional* consequence permits courts to fashion one. Again, however, the point of all these provisions is simply to trigger and channel patent litigation. When a sponsor already may sue on all patents, Congress concluded there is no need for additional patent litigation-channeling consequences. Sandoz Br. 60-63 (explaining notice provision inapplicable in these circumstances).

b. Congress elsewhere provided for an injunction but not in subsection (l)(8)

Sandoz explained (at 51-52) that the statute elsewhere expressly authorizes an injunction, which confirms that no injunction is available to enforce the notice provision. The statute provides that violation of certain confidentiality provisions "shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to

be an appropriate and necessary remedy for any violation or threatened violation." 42 U.S.C. § 262(*l*)(1)(H). Amgen argues (at 50) that this provision does not provide a remedy but merely "tells courts how to *apply* the traditional factors for equitable relief." It is difficult to construe a provision expressly stating that "injunctive relief" is both "appropriate and necessary" as anything but an authorization to provide it. Regardless, the absence of any analogue in the notice provision is powerful evidence that Congress did not intend an injunction to be available.

C. By Delaying Launch Of Every Biosimilar By 180 Days, The Federal Circuit's Ruling Disrupts The Careful Balance Congress Struck

As Sandoz showed (at 56-60), the Federal Circuit's decision delays all biosimilars' introduction by 180 days. Given Congress's intense focus on the length of the exclusivity period during the legislative process, Congress could not have silently intended the 12-year period to be 12 years and 180 days. *Ibid.*; Biosimilars Council Br. 14-17.

The statute provides that a biosimilar license may be made "effective" 12 years after the first licensure of the reference product, 42 U.S.C. § 262(k)(7)(A), and that a biosimilar may be introduced once a license is "in effect," *id.* § 262(a)(1)(A). Yet, under Amgen's reading, no biosimilar could ever be introduced at 12 years—all would have to wait until 12 years plus 180 days. Sandoz Br. 56-57. Amgen responds (at 52) that

the "approval remains effective" during the 180 days but that "it is only a necessary condition" for marketing, "not a sufficient one." But it would have been bizarre for Congress to use the word "effective" to describe a license that would always be *in*effective for 180 days.

Amgen also states (at 52) that "there is nothing unusual about delaying the market entry of a drug to facilitate orderly patent litigation" and points to Hatch-Waxman, which provides an "automatic stay of FDA approval" for adjudication of patent claims. This proves Sandoz's point. Had Congress intended an analogous stay of FDA approval here, it would have provided one expressly. Instead, "Congress declined to link FDA approval to a single provision in subsection (*l*)." Pet. App. 53a (Chen, J., dissenting). Moreover, the 180-day stay would perversely apply even when there are *no* patents to litigate. Sandoz Br. 40-41; Apotex Br. 19-20.

Amgen contends that "Sandoz and its corporate parent (Novartis) proposed precisely such a system" of delayed marketing "during the legislative process." Br. 53. This is just one example of so-called "legislative history" on which Amgen and its amici rely. This Court recently emphasized that "floor statements by individual legislators rank among the least illuminating forms of legislative history." *NLRB v. SW Gen.*, No. 15-1251, slip op. at 16 (Mar. 21, 2017). Yet Amgen and its amici rely on even less illuminating sources: witness statements at hearings before earlier Congresses, *e.g.*, Amgen Br. 10, 62, and earlier unenacted bills,

e.g., Amgen Br. 9, 45. Even if considered, Novartis's letter would be irrelevant. It addressed a fundamentally different proposal to have *no* pre-approval resolution of patent disputes. Ltr. From Paulo Costa, Novartis Corp., to Reps. Pallone & Deal 26-27 (May 1, 2008). Congress rejected that approach, providing for patent dispute resolution *before* licensure.

Moreover, if other such statements were considered, they would support Sandoz's reading. In discussing a predecessor bill, Representative Eshoo, the Biosimilars Act's principal sponsor, stated that the bill was intended to "ensure that all patent disputes involving a biosimilar are resolved *before, and I emphasize the word before*, the expiration of the data-exclusivity period." *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 9 (2009) ("*Biologics and Biosimilars Hearing*") (emphasis added). A representative of Amgen's amicus BIO similarly stated that "[n]early all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues *before a biosimilar is approved*." Jeffrey P. Kushan, Prepared Statement on Behalf of Biotechnology Indus. Org., *Biologics and Biosimilars Hearing* 77 (emphasis added). Such statements refute Amgen's portrayal of congressional intent to channel litigation *after* FDA approval.

Amgen notably does not endorse what it calls the Federal Circuit's "speculat[ion]" in *Apotex* that "the FDA might be able to 'issue a license before the

11.5-year mark and deem the license to take effect on the 12-year date,' allowing the applicant to give its marketing notice 180 days before the end of the 12-year period." Br. 56 (quoting 827 F.3d at 1062). Nor does Amgen respond to Sandoz's explanation (at 58-59) why that would not restore the 12-year exclusivity period Congress intended. Moreover, even if feasible, the Federal Circuit's workaround would apply only where the application was approved during the exclusivity period. That is a distant prospect—"[t]oday, many biosimilar applications are pending for blockbuster biologics where the statutory market exclusivity has already expired." Coherus Br. 13-14.

III. THE FEDERAL CIRCUIT ERRONEOUSLY DIVORCED THE NOTICE PROVISION FROM THE PATENT RESOLUTION SCHEME

Sandoz and the government each showed in standalone sections of their briefs (Sandoz Br. 60-63; U.S. Br. 32-33) that the notice of commercial marketing provision is inapplicable where, as here, the parties did not engage in the information exchange process. Pet. App. 48a-52a (Chen, J., dissenting). And Sandoz explained (at 6-7, 60) this interpretation independently warrants reversal. Amgen offers no response.

RESPONSE IN NO. 15-1195

SUMMARY OF ARGUMENT

I. Read in the context of the entire Biosimilars Act, the "shall" provision in Section 262(*l*)(2)(A) is a condition precedent to engaging in the information exchange process, not a mandatory requirement in all circumstances. To take advantage of that exchange process, the applicant must provide the sponsor its application within 20 days of notice that the FDA has accepted it for review. This interpretation is consistent with uses of "shall" in subsection (*l*), as well as in other statutory schemes.

This reading also furthers Congress's carefully reticulated system for early litigation of any patent rights. Congress balanced the interests between sponsors and applicants, determined what the consequences of noncompliance should be at each step of the process, and allowed the parties to weigh the benefits and burdens of each option. Congress determined that if the application is not provided, allowing the sponsor to bring an immediate infringement action is the proper recourse. Sandoz did not act unlawfully in taking a path expressly laid out by Congress.

II. Even if subsection (*l*)(2) is mandatory in all circumstances, a sponsor would not be entitled to an extra-statutory injunction to "enforce" it. Courts may not fashion causes of action and injunctive remedies on top of the consequences Congress provided.

ARGUMENT

I. THE BIOSIMILARS ACT DOES NOT MANDATE THAT THE INFORMATION EXCHANGE PROCESS BE FOLLOWED IN ALL CIRCUMSTANCES

The Court does not interpret a statutory provision "in isolation." *Star Athletica v. Varsity Brands*, No. 15-866, slip op. at 6 (Mar. 22, 2017). Instead, it "look[s] to the provisions of the whole law to determine [the provision's] meaning." *Id.* at 7 (quotation marks and citation omitted). Applying these principles, the court of appeals correctly concluded that "Sandoz did not violate the BPCIA by not disclosing its [application] and the manufacturing information according to § 262(*l*)(2)(A)." Pet. App. 27a. Because Amgen's state law claims required an unlawful act, the court of appeals correctly affirmed their dismissal. Pet. App. 26a-27a, 28a-29a.

A. Text And Structure Demonstrate That "Shall Provide" In Section 262(*l*)(2)(A) Is A Mandatory Condition Precedent

1. Subsection (l)(2)(A) is a condition precedent to the information exchange process

The Act's patent resolution regime goes well beyond the Section 262(*l*) information exchange process on which Amgen focuses. As Sandoz explained (at 10-17), the Act made interlocking amendments to Titles 28, 35, and 42, creating new artificial acts of infringement to allow early resolution of patent

disputes before *actual* infringement. The actions and inactions of the applicant and sponsor determine which party can sue under these provisions, as well as any suit's scope and timing. Sandoz Br. 10-17. Regardless of the paths taken, the ultimate destination is the same: patent litigation.

One route to pre-approval litigation is to complete the information exchange process. To start it, the applicant "shall provide to the reference product sponsor a copy of the application submitted" within 20 days of the FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). But the Act expressly contemplates that an applicant might not do so. In that event, nonprovision of the application is an act of artificial infringement; the information exchange process does not happen; and the sponsor may sue immediately, as Amgen did here. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii); *see* CA JA A79-A80. Rather than allowing parties to compel compliance, the statute incentivizes their participation in the process. Pet. App. 71a; *infra* pp. 35-36.

2. *Amgen improperly focuses on words in isolation*

"Shall." Amgen relies principally (at 58) on the notion that "'shall' is ordinarily 'the language of command.'" But an interpretation that is "plausible in the abstract" fails when it is "ultimately inconsistent with both the text and context of the statute as a whole." *Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016). Despite its supposed embrace (at 1) of the statute "as written,"

Amgen disregards the statute's specification of what follows when a "shall" condition is not satisfied.

Sandoz agrees that "shall" in Section 262(*l*)(2)(A) is mandatory. It specifies an action that an applicant *must* take to proceed with the process: *if* an applicant wishes to engage in the information exchange, it "shall" timely provide its application. 42 U.S.C. § 262(*l*)(2)(A); *see* Pet. App. 69a. When that condition is unsatisfied, the parties shift to a different patent resolution track. "*If* a subsection (k) applicant fails to provide [its] application," 42 U.S.C. § 262(*l*)(9)(C) (emphasis added), the sponsor may immediately commence a declaratory judgment action under the artificial act of infringement provision created for precisely that circumstance. Pet. App. 15a-17a; 35 U.S.C. § 271(e)(2)(C)(ii).

This reading is confirmed by Section 262(*l*)(6), which provides that after the information exchange process, "the reference product sponsor *shall* bring an action for patent infringement" on specified patents within 30 days. 42 U.S.C. § 262(*l*)(6) (emphasis added). If "shall" were mandatory in all circumstances, then a sponsor failing to timely sue would "violate" subsection (*l*)(6). That cannot be right. Congress obviously did not make it "unlawful" not to file a lawsuit. Indeed, compelling such protected activity would create serious constitutional concerns. *Cf. Bill Johnson's Restaurants v. NLRB*, 461 U.S. 731, 741 (1983).

Instead, the statute incentivizes sponsors to sue within 30 days by providing consequences if they do

not. Expressly envisioning that a sponsor might not sue until "*after* the expiration of the 30-day period," the statute limits the sponsor's remedies in that event. 35 U.S.C. § 271(e)(6)(A)(ii)(I), (B) (emphasis added). Thus, the requirement that a sponsor "shall" sue within a specified timeframe is a condition precedent to other statutory benefits. *Id.* § 271(e)(4), (6)(B). So too with the "shall" provision in subsection (*l*)(2).

"***May.***" Amgen contends (at 58-59) that its view is supported by the "contrast" between the statute's use of "shall" and "may"; its description of provision of the application as "required"; and its reference to non-provision as a "fail[ure]." These arguments again ignore the broader context.

Subsection (*l*)(2) uses "shall" and "may" to distinguish between the information that "shall" be provided as a condition precedent to participating in the information exchange, 42 U.S.C. § 262(*l*)(2)(A), and the additional information that "may" be optionally provided but is not necessary to proceed to the next step, *id.* § 262(*l*)(2)(B). Similarly, the statute uses "required" to describe the same, condition-precedent-satisfying information. *Id.* § 262(*l*)(1)(B)(i); *id.* § 262(*l*)(9)(A), (C).

"***Fails.***" Nor by describing noncompliance as a "fail[ure]" does the statute mandate the provision of subsection (*l*)(2)(A) information in all circumstances. *Id.* § 262(*l*)(9)(C). The statute uses "fails to provide the application" and "application not provided" interchangeably. *Ibid.* ("Subsection (k) application not provided—If a subsection (k) applicant fails to provide the

application * * *"). Elsewhere it uses "fail" when there plainly is no duty to perform. Subsection (*l*)(4)(B), titled "Failure to reach agreement," discusses what happens if the parties "fail to agree" on a patent list. *Id.* § 262(*l*)(4)(B). Yet there is certainly no means to compel agreement. Instead—just as when an applicant "fails" to provide its application—the parties' "[f]ailure" to agree simply shifts them to a different patent resolution track. *Id.* § 262(*l*)(5) (titled "Patent resolution if no agreement").

This same contingent structure pervades subsection (*l*): multiple "shall" provisions are coupled with statutory consequences for noncompliance. Sandoz Br. 12 (flowchart).

"Must" in discovery rules. Amgen points to a discovery rule stating that a party in pending litigation "'*must*, without awaiting a discovery request, provide' certain information." Br. 60 (quoting Fed. R. Civ. P. 26(a) (emphasis by Amgen)). But whether that rule is "mandatory" says nothing about the meaning of the Biosimilars Act. Moreover, the discovery rules expressly provide what the Biosimilars Act does not—a provision allowing parties to request the court "to compel disclosure." Fed. R. Civ. P. 37(a)(3)(A).

More analogous are statutes and rules mandating that a party act by a deadline—or else suffer consequences. For example, one of this Court's jurisdictional statutes provides that a direct appeal "*shall be taken* within thirty days after the entry" of an order. 28 U.S.C. § 2101(a) (emphasis added); *see also, e.g.*,

Fed. R. App. P. 4(b)(1)(A) ("a defendant's notice of appeal *must be filed* in the district court within 14 days after the later of" certain events). But a party failing to take such an appeal is not "violating" that provision, nor could it be compelled (under federal or state law) to appeal. Rather, the party would suffer the consequences of failing to do so, by having any late appeal dismissed and the underlying order left undisturbed. *Bowles v. Russell*, 551 U.S. 205, 211-13 (2007).

B. Interpreting Section 262(*l*)(2)(A) As A Condition Precedent Advances The Biosimilars Act's Purposes

1. Congress carefully balanced the interests of sponsors and applicants

Reading Section 262(*l*)(2)(A) as a condition precedent to one path to patent litigation fulfills Congress's purpose: pre-approval litigation on potential patent rights. Congress demonstrated its purpose by creating acts of artificial infringement—both for when the information exchange takes place *and* for when it does not. 35 U.S.C. § 271(e)(2)(C).

This regime offers tradeoffs for both sponsors and applicants. Where, as here, the applicant does not participate in the information exchange process, there are benefits to the sponsor and costs to the applicant. The sponsor gains far more control over the scope and timing of any infringement suit. It can sue immediately on all its patents. Or the sponsor can wait until the biosimilar's approval, forcing the applicant to launch its product without knowing whether it faces

patent damages. 42 U.S.C. § 262(*l*)(9)(B)-(C); 35 U.S.C. § 271(e)(2)(C)(ii). The applicant forfeits its ability to gain certainty by filing its own declaratory judgment action and its pre-litigation look at potentially relevant patents. 42 U.S.C. § 262(*l*)(3)(A), (9)(C). An applicant may nevertheless choose this path if it seeks quick resolution, believes that no unexpired, relevant patents will remain after the exclusivity period, and/or has concerns about providing its application without a court protective order. Pet. App. 72a.

By contrast, participating in the information exchange process benefits applicants. As Amgen's amicus acknowledges, it gives "applicants significant control over the timing and scope of patent litigation." BIO Br. 23. Not only does that path give the applicant a temporary safe harbor from litigation, 42 U.S.C. § 262(*l*)(9)(A), but it forces the sponsor to identify the patents it believes are valid and infringed or forfeit its ability to sue for infringement, *id.* § 262(*l*)(3)(A); 35 U.S.C. § 271(e)(6)(C). It allows the applicant to control how many patents are initially litigated. 42 U.S.C. § 262(*l*)(4), (5). And following the process increases the chance of an infringement suit by the sponsor within a specified timeframe, because otherwise its remedies would be limited. *Id.* § 262(*l*)(6); 35 U.S.C. § 271(e)(6)(B).

2. *Amgen's resort to policy arguments and faux "legislative history" is unavailing*

In arguing for its rigidly separated two-phase mandatory system, Amgen advances policy arguments unmoored from the statute and cites unenacted bills from previous Congresses.

First, Amgen posits (at 60-61) that if an applicant does not initiate the information exchange process by providing its application, a sponsor might not know which patents the biosimilar would infringe. But Congress concluded otherwise, expressly giving the sponsor the immediate right to sue for artificial infringement if the application is not provided. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). Amgen did exactly that here. CA JA A79-A80 (infringement claim).

Contrary to Amgen's assertions (at 61), such a suit will protect any valid patent claims. Like all other patentee plaintiffs, a sponsor will have access to normal discovery tools. The sponsor can obtain the biosimilar application under a protective order, just as Amgen did here. Pet. App. 17a. Competitors rarely have access to each other's confidential manufacturing processes before litigating. Indeed, knowing that the applicant's biologic is similar enough to qualify as a biosimilar gives the sponsor more information than the ordinary competitor, not less. *Contra* Amgen Br. 61. And competitors regularly file infringement suits after diligent investigation, such as pre-suit letters seeking information about manufacturing processes. If the

response is inadequate, the patentee can sue without violating Federal Rule of Civil Procedure 11. *Hoffman-La Roche v. Invamed*, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000). Then patentees use discovery to learn detailed information and amend their complaint if necessary. Pet. App. 17a, 72a n.6; Biosimilars Council Br. 31-33.[7]

Second, Amgen contends (at 62) that the applicant must always produce its application because the disclosures facilitate the later information exchange steps, which can streamline litigation. To start, there is nothing streamlined about allowing parties to sue every 60 days to challenge the other side's compliance with the information exchange. *E.g.*, Compl., *Genentech v. Amgen*, No. 1:17-cv-165 (D. Del. 2017) (suit to force *Amgen* to provide more information under subsection (*l*)(2)(A) about Amgen's biosimilar). Moreover, Amgen's position ignores that Congress envisioned more than one path to litigation. Sandoz Br. 12. And as the district court recognized, a forced march through the information exchange (even without pit-stops for injunction litigation) may sometimes be inefficient. Pet. App. 72a.

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[7] Amgen's discussion (at 61-62) of its suit against Hospira is immaterial. Amgen sued Hospira under subsection (*l*)(6) on two patents. Amgen CA Br. 4-12, Dkt.28, No. 2016-2179 (Fed. Cir. Sept. 12, 2016). Yet Amgen sought discovery regarding possible infringement of *different* patents, on which it could not sue because of their absence from its subsection (*l*)(3) list. *Ibid.*; *see* 42 U.S.C. § 262(*l*)(6). By contrast to the limited scope of a subsection (*l*)(6) suit, a declaratory judgment suit triggered by non-provision of the application can involve any patent (if there is a product or use patent), Sandoz Br. 13, so discovery would not be similarly constrained.

Where, as here, an applicant "values expedience over risk mitigation," the statute allows it to forgo the process and subject itself to immediate suit. *Ibid.* The information exchange process "could take up to 230 days" after the application is provided—"just to *commence* patent litigation." *Ibid.* (emphasis added). Sandoz therefore "traded in the chance to narrow the scope of potential litigation with Amgen through subsection (*l*)'s steps, in exchange for the expediency of an immediate lawsuit." Pet. App. 73a.[8]

Third, Amgen asserts (at 62) that allowing an applicant to forgo the information exchange would "unfairly limit the sponsor's remedies" because the injunction authorized by 35 U.S.C. § 271(e)(4)(D) is otherwise unavailable. Amgen's characterization (at 63) of this provision as providing a "mandatory" injunction is contrary to this Court's consistent direction that injunctions require examination of "traditional equitable considerations." *eBay*, 547 at 392-93.

Regardless, the Section 271(e)(4)(D) injunction is available only in limited circumstances: when patent litigation proceeds to a final decision from

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[8] BIO contends (at 23) the need for expediency is diminishing. That is wrong. Most biosimilars in development reference biologics for which exclusivity has run. *Supra* p. 29. And whenever the applicant believes all relevant patents will have expired during the 12-year exclusivity period (which was intended to mirror patent protection, Sandoz Br. 10), it might forgo the information exchange.

the Federal Circuit before the exclusivity period expires. 35 U.S.C. § 271(e)(4)(D) (cross-referencing 42 U.S.C. § 262(k)(6)-(7)). Amgen's exclusivity expired long ago, so it could not have accessed this provision even if Sandoz had provided its application. Moreover, the statute separately allows injunctions for patent infringement, *id.* § 271(e)(4)(B)—without any condition precedent related to the information exchange process.

Finally, Amgen contends (at 63) that "Congress considered and rejected a permissive rather than mandatory" scheme. But unenacted legislation from previous Congresses sheds no light here. *Star Athletica*, slip op. at 17 (arguments from unenacted bills "lack[] persuasive significance in most circumstances") (quotation marks and citation omitted). Those bills proposed a very different information exchange process and, unlike the Biosimilars Act, created no consequences for the applicant's decision not to initiate or complete it. *Compare* 42 U.S.C. § 262(*l*)(9)(B), (C), *with* H.R. 6257, H.R. 1427, S. 623.

II. NO EXTRA-STATUTORY RIGHT OF ACTION TO COMPEL PROVISION OF THE BIOSIMILAR APPLICATION EXISTS

Even if disclosure of the application were mandatory, a sponsor cannot secure an injunction mandating disclosure. The statute creates no cause of action for that remedy.

Amgen contends (at 64) that the Court need not decide whether a federal injunction is available

because it sought a state law injunction. But Amgen fails to note (and thus waives any challenge to) the Federal Circuit's conclusions that such an injunction is unavailable on state law grounds. Pet. App. 27a, 29a.[9] Sandoz opposed Amgen's conditional cross-petition on that basis. 15-1195 Opp. 24-32. If the Court granted the cross-petition to decide whether federal law authorizes an injunction to "enforce" subsection (*l*)(2), it should answer that question "no" and affirm.

As it does for subsection (*l*)(8)(A), Amgen contends (at 64-65) that courts have "inherent power to grant equitable relief" to enforce subsection (*l*)(2) and, in the alternative, that a private right of action should be inferred. Those arguments fail for the reasons above. *Supra* pp. 20-28.

Implying a private right of action to "enforce" subsection (*l*)(2) would be particularly inappropriate given that Congress expressly specified consequences for non-provision of the application: an artificial act of infringement allowing immediate patent litigation by the sponsor, 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). *Supra* pp. 33-34.

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[9] Moreover, any attempt to use California law to "enforce" the Biosimilars Act would be preempted and would in any event support an injunction only in California. *Supra* pp. 19-20.

Amgen complains (at 65) these provisions do not "provide any remedy" for a "violation" of subsection (*l*)(2)(A). This complaint lacks merit for the same reasons as it did for subsection (*l*)(8)(A). *Supra* pp. 25-26. Regardless whether these provisions are themselves "remedial," they specify the only consequences Congress provided for noncompliance with subsection (*l*)(2): access to litigation to obtain *patent remedies*. Indeed, Congress specified that patent remedies are "the *only* remedies which may be granted by a court" for an artificial act of infringement under the Biosimilars Act. 35 U.S.C. § 271(e)(4) (emphasis added). In a scheme that "concerns one thing: patent litigation," Pet. App. 45a (Chen, J., dissenting), those remedies are fully adequate.

CONCLUSION

The Federal Circuit's judgment on the notice of commercial marketing should be reversed. Its judgment on the biosimilar application should be affirmed.

Respectfully submitted,

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